

OCT 30 2001

Oey, Jan

From: Kinser, Robin D.
Sent: Tuesday, October 30, 2001 4:24 PM
To: 'Jill Schultz'
Cc: Kinser, Robin D.; Oey, Jan
Subject: RE: MDA plasma validation data

Jill--The MDA data are acceptable except for the processed sample stability and stock solution stability. I thought an earlier email indicated that further stability data were forthcoming, but I don't think I've received any. All that stands in the way of authorization to run specimens right now is some further info on stability, either written or conveyed to me by telephone. . . --Robin

-----Original Message-----

From: Jill Schultz [SMTP:jill.schultz@Covance.Com]
Sent: Tuesday, October 30, 2001 4:04 PM
To: Holt.Klausvon@pmintl.ch; kuhl.peter@pmintl.ch; rustemeier.Klaus@pmintl.ch; Schepers.Georg@pmintl.ch; Stabbert.Regina@pmintl.ch; tricker.anthony@pmintl.ch; Hans-Juergen.Roethig@pmusa.com; Jan.Oey@pmusa.com; robin.d.kinser@pmusa.com
Subject: MDA plasma validation data

As requested, please find attached as follows:

1) Calibration curve for MDA in plasma (Line.doc).

2) Representative chromatogram for an MDA QC concentration of 1 umol/L (Chrom.doc).

Analytical method summary: Plasma samples are thawed in a water bath (nom. 25 to 30xC) and then subjected to a protein precipitation step.

After centrifugation the supernatant is derivatised in the presence of an antioxidant, to yield a fluorescent derivative. The derivative is quantified using HPLC and a fluorescence detector.

The processed samples were not stable when stored for 24 hours before injection.

To avoid any potential confusion, we will forward the glucuronide data by separate e-mail.

Best regards,

Jill

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